Department in the field of mental health. The Council reviews applications for grants-in-aid relating to research and training in the field of mental health and makes recommendations to the Secretary with respect to approval of applications for, and amount of, these grants.

Substantive information may be obtained from the contact persons listed above. Summaries of the meetings and rosters of committee members may be obtained as follows: NIAAA: Ms. Diana Widner, Committee Management Officer, Room 16C20, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443–4375. NIMH: Ms. Joanna Kieffer, Committee Management Officer, Room 9–95, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443–4333.

Dated: November 14, 1986.

Estelle O. Brown,

Committee Management Assistant, Alcohol, Drug Abuse, and Mental Health Administration.

[FR Doc. 86–26153 Filed 11–19–86; 8:45 am]

BILLING CODE 4160–20–M

Food and Drug Administration

[Docket No. 86F–0373]

Combibloc, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Combibloc, Inc., has filed a petition proposing that the food additive regulations be amended to provide for an increase in the level of residual hydrogen peroxide that may be present when hydrogen peroxide is used to sterilize polymeric food-contact surfaces.

FOR FURTHER INFORMATION CONTACT: Thomas C. Brown, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 6B3962) has been filed by Combibloc, Inc., 4800 Roberts Rd., Columbus, OH 43228, proposing that § 178.1005 *Hydrogen peroxide solution* (21 CFR 178.1005) be amended to provide for an increase in the hydrogen peroxide limitation from the current 0.1 part per million to a level of 0.5 part per million. This will provide for an increase in the level of residual hydrogen peroxide that may be present when hydrogen peroxide is used to sterilize polymeric food-contact surfaces.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: November 5, 1986.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 86–26136 Filed 11–19–86; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 86E–0357]

Determination of Regulatory Review Period for Purposes of Patent Extension; Orthoclone OKT*3

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Orthoclone OKT*3 and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESS: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) generally provides that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under that act, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Orthoclone OKT*3 (muromonab CD3) which is indicated for the treatment of acute allograft rejection in renal transplant patients. Based on this approval, Ortho Pharmaceutical Corp. now seeks patent term restoration.

FDA has determined that the applicable regulatory review period for Orthoclone OKT*3 is 2,301 days. Of this time, 1,488 days occurred during the testing phase of the regulatory review period, while 813 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective:* March 3, 1980. The applicant states that investigational exemption (IND) time for the drug product is inapplicable. However, FDA records indicate that an IND for the product became effective on March 3, 1980.

2. *The date the product license application was initially submitted with respect to the human drug product under section 351 of the Public Health Service Act:* March 29, 1984. FDA has verified that the product license application for the drug product was filed on March 29, 1984.

3. *The date the application was approved:* June 19, 1986. FDA verified that product license 996 for the drug product was approved on June 19, 1986.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension.

In its application for patent extension, this applicant seeks 201 days of patent extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before January 20, 1987, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before May 19, 1987, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, Part 1, 98th Cong., 2d Sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 14, 1986.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 86–26157 Filed 11–19–86; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 86M–0422]

Allergan Pharmaceuticals, Inc.; Premarket Approval of the Lens Plus OXYSEPT™ Disinfection System

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Allergan Pharmaceuticals, Inc., Irvine, CA, for premarket approval, under the Medical Device Amendments of 1976, of the Lens Plus OXYSEPT™ DISINFECTION SYSTEM for use with soft (hydrophilic) contact lenses. After reviewing the recommendation of the Ophthalmic Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant of the approval of the application.

DATE: Petitions for administrative review by December 22, 1986.

ADDRESS: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: David M. Whipple, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7940.

SUPPLEMENTARY INFORMATION: On November 29, 1985, Allergan Pharmaceuticals, Inc., Irvine, CA 92715, submitted to CDRH an application for premarket approval of the Lens Plus OXYSEPT™ DISINFECTION SYSTEM. The Lens Plus OXYSEPT™ DISINFECTION SYSTEM is a 3 percent hydrogen peroxide system consisting of the OXYSEPT™ 1 Disinfecting Solution, the OXYSEPT™ 2 or OXYSEPT™ 2/np Rinse and Neutralizer, and the OXYCUP™ Lens Case. The Lens Plus OXYSEPT™ DISNFECTION SYSTEM is indicated for use to disinfect, neutralize, and store soft (hydrophilic) contact lenses.

On May 23, 1986, the Ophthalmic Devices Panel, an FDA advisory committee, reviewed and recommended approval of the application. On September 30, 1986, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

A copy of all approved labeling is available for public inspection at CDRH—contact David M. Whipple (HFZ–460), address above.

The labeling of the Lens Plus OXYSEPT™ DISINFECTION SYSTEM states that the system is indicated for use to disinfect, neutralize, and store soft (hydrophilic) contact lenses. Manufacturers of soft (hydrophilic) contact lenses that have been approved for marketing are advised that whenever CDRH publishes a notice in the **Federal Register** of the approval of a new solution for use with an approved soft contact lens, the manufacturer of each lens shall correct its labeling to refer to the new solution at the next printing or at such other time as CDRH prescribes by letter to the applicant.

Opportunity for Administrative Review

Section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g)), for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under Part 12 (21 CFR Part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register.** If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may at any time on or before December 22, 1986, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h), 90 Stat. 554–555, 571 (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: November 13, 1986.

John C. Villforth,

Director, Center for Devices and Radiological Health.

[FR Doc. 86–26154 Filed 11–19–86; 8:45 am]

BILLING CODE 4160–01–M

Health Care Financing Administration

[OACT–014–N]

Medicare Program; Omnibus Budget Reconciliation Act of 1986; Effect of Provisions on Part A Deductible, Part A and B Premiums, and Economic Index

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

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